What is the relationship between the intake of soy protein and blood pressure among adults without hypertension?

Conclusion

A limited and inconsistent body of evidence shows that soy protein intake does not provide any unique benefits in blood pressure control.

Grade: Limited

Overall strength of the available supporting evidence: Strong; Moderate; Limited; Expert Opinion Only; Grade not assignable For additional information regarding how to interpret grades, click here.

Evidence Summary Overview

This review included five studies examining the relationship between soy protein and blood pressure (BP) or hypertension (HTN) among adults without HTN published since 2000. Three randomized controlled trials (RCTs) (He, 2005; Liao, 2007; Teede, 2002), one prospective cohort study (Yang, 2005) and one cross-sectional study (Pan, 2008) were included in the review. All of the studies were conducted outside of the US.

- He et al, (2005) and Teede et al, (2002) conducted RCTs that included 40g of soy protein consumed per day over three months. In both studies, participants receiving soy protein supplementation experienced a significant decrease in SBP and DBP compared to the control groups. Liao and colleagues (2007) did not observe significant changes in SBP or DBP among participants consuming soy protein as the only protein source vs. a control diet with animal and plant protein for eight weeks; the groups consumed an isocaloric diet providing 1,200kcal per day
- In the Shanghai Women's Health Study, SBP and DBP were lower in women who consumed ≥2.5g soy protein per day than in women consuming <2.5g per day (Yang, 2005). In cross-sectional analyses of the Nutrition and Health of Aging Population Project in China, soy protein intake and elevated BP were inversely associated in men, but not women (Pan, 2008); median soy protein in quartile one and quartile four of this study were 3g per day and 16g per day, respectively.

Evidence Summary Paragraphs

He et al, 2005 (positive quality), a double-blind, RCT conducted in the People's Republic of China, examined the effect of soybean protein supplementation on BP. Participants were adults with pre-hypertension or stage 1 HTN (initial N=302, final N=276; approximately 50% female; age 35 to 64 years) who were randomly assigned to receive 40 g of isolated soybean protein supplement per day in cookies for 12 weeks or 40g of complex carbohydrate from wheat in cookies during the same period. Compliance was measured by participants returning uneaten cookies (93% compliance for each group). Participants were instructed to reduce other food intake so that total energy intake would remain constant. Blood pressure was assessed by study personnel at baseline, six weeks and 12 weeks. At baseline, mean (SD) SBP and DBP were 135.0 (10.9) mmHg and 84.7 (6.9) mmHg,

respectively. Compared with the control group, the net changes in SBP and DBP were -4.31mmHg (95% CI: -2.11, -6.51mmHg; P<0.001) and -2.76mmHg (95% CI: -1.35, -4.16mm Hg; P<0.001), respectively, after the 12-week intervention. For both SBP and DBP, the net reduction was greater in those with HTN than in those who were normotensive. The interaction between hypertensive status and BP effect of soybean protein was significant for both SBP (P=0.01) and DBP (P=0.007). The net changes in SBP and DBP reductions were -7.88mmHg (95% CI: -4.66, -11.1mmHg) and -5.27mmHg (95% CI: -3.05, -7.49mmHg), respectively, in persons with HTN and -2.34mmHg (95% CI: 0.48, -5.17mmHg) and -1.28mmHg (95% CI: 0.52, -3.07mmHg), respectively, in those without HTN. (The study was not designed to have sufficient statistical power to test for a BP reduction effect within sub-groups.) The authors concluded that soybean protein supplementation resulted in a reduction in SBP and DBP. Further, they suggested that increased intake of soybean protein may play an important role in preventing and treating HTN.

Teede et al, 2002 (positive quality) determined the effect of dietary soy supplementation on lipid parameters, BP, arterial compliance and endothelial function in an RCT in Australia. Participants were normotensive men and postmenopausal women (initial N=213, final N=179; 54% male; age 50 to 75 years) who received either soy protein isolate (40g soy protein, 118mg isoflavones) or casein placebo for three months. Participants consumed the supplements twice daily (in beverage form) in addition to their usual diet with no other modifications. Measurements were completed at baseline and three months. After intervention in the soy group, compared with casein placebo, a significant fall in BP was observed (P<0.01) encompassing mean change (±SEM) in SBP (-7.5±1.2 vs. -3.6±1.1mmHg, P<0.05), DBP (-4.3±0.8 vs. -1.9±0.7mmHg, P<0.05) and mean BP (-5.5±1 vs. -0.9±1mmHg, P<0.008). The authors concluded that soy improved BP in normotensive men and postmenopausal women.

Liao et al, 2007 (positive quality), an RCT, examined the effects of a soy-based diet compared with a traditional low-calorie diet on weight loss and blood lipid levels in 30 obese adults (mean BMI 29-30kg/m^2; 80% female) in China. Participants were randomized to two groups: The soy-based low-calorie group consumed soy protein as the only protein source, and the traditional low-calorie group consumed two-thirds animal protein and the rest plant protein in a 1,200kcal per day diet for eight weeks. Anthropometric data were acquired every week, and biochemical data from before and after the eight-week experiment were compared. Systolic blood pressure and DBP were not significantly (NS) different within either group or between groups between baseline and eight weeks.

Yang et al, 2005 (neutral quality) examined the association between usual intake of soy foods and BP among 45,694 women (age 40 to 70 years) in the Shanghai Women's Health Study. Women were excluded from analyses if they had a history of HTN or reported taking anti-hypertensive medications. Usual intake of soy foods over the previous 12 months was assessed at baseline with a validated food frequency questionnaire (FFQ) during a face-to-face interview. The questionnaire included 11 soy food items (i.e., tofu, soy milk, fried bean curd, bean curd cake and other kinds of soy products), covering virtually all soy foods consumed in urban Shanghai. Fresh and dried soybeans were also included. Blood pressure was measured two to three years after the baseline survey by study personnel. Soy protein intake was inversely associated with both SBP and DBP after adjustment for age, BMI and lifestyle and other dietary factors. The adjusted mean SBP was 1.9 mmHg lower (95% CI: -3.0, -0.8mmHg; P for trend =0.01) and the DBP was 0.9mmHg lower (95% CI: -1.6, -0.2mmHg; P for trend =0.009) in women who consumed ≥25g soy protein per day than in women consuming <2.5g per day. The authors concluded that usual intake of soy foods was significantly and inversely associated with both SBP and DBP.

Pan et al, 2008 (neutral quality) evaluated the association between soy protein intake and the risk of MetS and its components in a cross-sectional analysis of 2,811 adults (58% female; age 58.4+6.0

years) from the Nutrition and Health of Aging Population in China Project. Blood pressure was measured during physical examinations at local health stations or community clinics. Data on nutrient intake in the year prior to enrollment were derived from a quantitative FFQ that was administered during a personal interview. The FFQ included 74 food items and groups. Seven soy food items responsible for the majority of soy consumption were listed within the questionnaire, including fresh and dried soybeans, tofu, soy milk, jelly bean curd, soy sauce and other processed soy products. Soy protein intake and elevated BP were inversely associated in men (OR between extreme quartiles=0.59; 95% CI: 0.37, 0.95; P for trend=0.049), but NS association was observed for women (P for trend=0.284) or for men and women combined (P for trend=0.056).

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Author, Year, Study Design, Class, Rating	**Study**	**Location**	**Soy Protein Association (Pos, Neg, None)**
He J, Gu D et al, 2005 Study Design: Randomized controlled trial Class: A Rating:	Adults with prehypertension or stage 1 HTN.	The People's Republic of China.	(-) SBP, (-) DBP.
Liao et al 2007 Study Design: randomized intervention trial Class: A Rating:	Isocaloric Weight Loss Interventions.	China.	Ø SBP, Ø DBP.
Pan et al 2008 Study Design: cross sectional study Class: D Rating:	Nutrition and Health of Aging Population Project.	China.	(-) ↑ BP in men, Ø ↑ BP in women.

Teede HJ, Dalais FS et al, 2001 Study Design: RCT Class: A Rating:	Normotensive men and postmenopausal women.	Australia.	(-) BP, (-) SBP, (-) DBP.
Yang G, Shu XO et al, 2005 Study Design: Prospective cohort, longitudinal study Class: B Rating:	Shanghai Women's Health Study.	China.	(-) SBP, (-) DBP.

Research Design and Implementation Rating Summary
For a summary of the Research Design and Implementation Rating results, click here.

Worksheets

He J, Gu D, Wu X, Chen J, Duan X, Chen J, Whelton PK. Effect of soybean protein on blood pressure: A randomized, controlled trial. Ann Int Med. 2005; 143: 1-9.

Liao FH, Shieh MJ, Yang SC, Lin SH, Chien YW. Effectiveness of a soy-based compared with a traditional low-calorie diet on weight loss and lipid levels in overweight adults. Nutrition. 2007 Jul-Aug;23(7-8):551-6

Pan A, Franco OH, Ye J, Demark-Wahnefried W, Ye X, Yu Z, Li H, Lin X. Soy protein intake has sex-specific effects on the risk of metabolic syndrome in middle-aged and elderly Chinese. J Nutr. 2008 Dec;138(12):2413-21.

Teede HJ, Dalais FS, Kotsopoulos D, Liang Y, Davis S, McGrath BP. Dietary soy has both beneficial and potentially adverse cardiovascular effects: A placebo-controlled study in men and postmenopausal women. The Journal of Clinical Endocrinology and Metabolism, 2001; 86: 3,053-3,060.

Yang G, Shu X-O, Jin F, Zhang X, Li H-L, Li Q, Gao Y-T, Zheng W. Longitudinal study of soy food intake and blood pressure among middle-aged and elderly Chinese women. Am J Clin Nutr. 2005: 81: 1,012-1,017.